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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,105	08/15/2001	Fred S. Lamb	875.054US1	9991

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,105

Applicant(s)

LAMB ET AL.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 25, 26, 36, 37 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 27-35 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group VII (claims 22-42) with a species of active agent of tamoxifen in Paper No's 9 and 12 is acknowledged. The traversal is on the ground(s) that the claims VII and VIII are directed to related subject matter and the members of the Markush group in the species election are sufficiently few and the search and examination of all of the claims can be made without serious burden of the Office. This is not persuasive because each of the medical disorders are patentably distinct and independent and they have known different etiology. For example, erectile dysfunction is caused by many different disorders (i.e. psychological, substance abuse). Further the plurality of disclosed patentably distinct species have different chemical core and have acquired a separate status in the art as they differ by different chemical core. Therefore, the restriction for examination purposes as indicated in the last Office Action is deemed proper and made final. Accordingly, claims 1-21, 25, 26, 36, 37 and 43 are withdrawn from consideration since they are non-elected invention.

Claim Objections

Claim 24 is objected to because of the following informalities: The term "wherein" is duplicated in line 1 of claim 24. Appropriate correction is required.

Art Unit: 1617

The parenthetical term in claims 24 and 35 are redundant. It is suggested to use a single appropriate chemical name. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-24, 27-29, 32-35 and 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Stromberg (U.S. Patent No. 5,470,883).

With regard to claims 22-24, 27-29, 32-35 and 38-42, Stromberg teaches a method of inhibiting or reversing peripheral vasoconstriction caused by adrenergic agent (e.g. norepinephrine, epinephrine) comprising administering orally a pharmacologically acceptable dose of tamoxifen. (abstract, column 1, lines 7-12, lines 46-50, column 2, lines 1-15 column 4, claims 1-8). Applicants' recitation in claims 33, 40-42 of an intended site (e.g. penile) would be inherent upon administration of tamoxifen to reverse vasoconstriction caused by norepinephrine as taught by Stromberg reference. (See Ex Party Novitiski 26 USPQ2d 1389).

Claims 22 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Grainger et al. (U.S. Patent No. 6,197,789B1) of record.

Grainger et al. on abstract, column 4, lines 7-16, column 5, line 65 through column 6, line 30, column 7, lines 15-33, column 8, lines 11-20, column 10, lines 51-57,

Art Unit: 1617

column 15, line 54, column 18, lines 34-44, column 24, lines 47-50, and column 25, lines 4-8, teach that Applicant's active agent is useful on vascular smooth muscle cells to inhibit the pathological activity of the smooth muscle cells, and to inhibit the activation of endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (U.S. Patent No. 6,197,789B1) of record.

Grainger et al. teachings as applied as before.

Art Unit: 1617

Grainger et al. do not teach the further administering the agents set forth in claim 31.

It would have been obvious to one of ordinary skill in the art to incorporate other agents similarly useful for the treatment of diabetes, hypertension and coronary artery disease together with the active agent (tamoxifen) in Grainger et al. which is also useful for the treatment of diabetes, hypertension and coronary artery blockage and they are related to the same treatment involving vascular smooth muscle cells. One would have been motivated to employ other agents set forth in claim 31 together with tamoxifen in order to achieve at least an additive effect in treatment of diseases well known to be treated by tamoxifen as well taught by Grainger et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sreenivasan Padmanabhan
Supervisory Examiner

Art Unit 1617 9/1/03

jmk
August 28, 2003